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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|--|-----------------|----------------------|-------------------------|-------------------------|--|
| 09/780,526 | 02/09/2001 | Imre Kovesdi | 206060 | 8376 | |
| 23460 | 7590 08/10/2004 | | EXAM | INER | |
| LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE | | | TRAN, MY | TRAN, MY CHAU T | |
| | | | ART UNIT | PAPER NUMBER | |
| CHICAGO, | IL 60601-6780 | | 1639 | | |
| | | | DATE MAILED: 08/10/200- | DATE MAILED: 08/10/2004 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | _ | | | |
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| Office Action Comment | | 09/780,526 | KOVESDI ET AL. | | | | |
| | Office Action Summary | Examiner | Art Unit | | | | |
| | | MY-CHAU T TRAN | 1639 | _ | | | |
| Period fo | The MAILING DATE of this communication or Reply | n appears on the cover sheet w | ith the correspondence address | | | | |
| | ORTENED STATUTORY PERIOD FOR RE | EDIVIQUET TO EVDIDE 2 N | MONTH(S) EDOM | | | | |
| | MAILING DATE OF THIS COMMUNICATION | | IONTH(S)TROM | | | | |
| | nsions of time may be available under the provisions of 37 CF SIX (6) MONTHS from the mailing date of this communication | | reply be timely filed | | | | |
| - If the | period for reply specified above is less than thirty (30) days, period for reply is specified above, the maximum statutory period for reply is specified above, the maximum statutory period for reply is specified above. | a reply within the statutory minimum of thi | | | | | |
| | re to reply within the set or extended period for reply will, by s reply received by the Office later than three months after the r | | | | | | |
| | ed patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | | |
| 1)⊠ | Responsive to communication(s) filed on 1 | 17 May 2004. | | | | | |
| / | This action is FINAL . 2b)⊠ This action is non-final. | | | | | | |
| 3) | Since this application is in condition for all | • | | | | | |
| | closed in accordance with the practice und | der <i>Ex parte Quayle</i> , 1935 C.I |). 11, 453 O.G. 213. | | | | |
| Dispositi | on of Claims | | | | | | |
| 4) | Claim(s) 1-12 is/are pending in the applica | ation. | | | | | |
| • | 4a) Of the above claim(s) 7,8,10 and 11 is/are withdrawn from consideration. | | | | | | |
| 5) | 5) Claim(s) is/are allowed. | | | | | | |
| 6) ⊠ | ☑ Claim(s) <u>1-6,9 and 12</u> is/are rejected. | | | | | | |
| - | Claim(s) is/are objected to. | | | | | | |
| 8)□ | Claim(s) are subject to restriction a | nd/or election requirement. | | | | | |
| Applicati | on Papers | | | | | | |
| | The specification is objected to by the Exar | miner | | | | | |
| 10)⊠ The drawing(s) filed on <u>09 February 2001</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner. | | | | | | | |
| | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| | Replacement drawing sheet(s) including the co | • , | ` ' | | | | |
| 11) | The oath or declaration is objected to by th | e Examiner. Note the attache | d Office Action or form PTO-152. | | | | |
| Priority (| ınder 35 U.S.C. § 119 | | | | | | |
| _ | | | C 440(a) (d) an (f) | | | | |
| , | Acknowledgment is made of a claim for for ☐ All b) ☐ Some * c) ☐ None of: | eign priority under 35 U.S.C. | 3 119(a)-(d) or (t). | | | | |
| a)(| ☐ All b)☐ Some * c)☐ None of: 1.☐ Certified copies of the priority docun | nents have been received | | | | | |
| | Certified copies of the priority docum Certified copies of the priority docum | | Application No | | | | |
| | 3. Copies of the certified copies of the | | | | | | |
| | application from the International Bu | | | | | | |
| * S | See the attached detailed Office action for a | , | received. | | | | |
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| Attachmen | t(s) | | | | | | |
| | e of References Cited (PTO-892) | | Summary (PTO-413) | | | | |
| | e of Draftsperson's Patent Drawing Review (PTO-948 mation Disclosure Statement(s) (PTO-1449 or PTO/SE | ·/ [] | s)/Mail Date nformal Patent Application (PTO-152) | | | | |
| | r No(s)/Mail Date | 6) Other: | · · · · · · · · · · · · · · · · · · · | | | | |
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DETAILED ACTION

Status of Claims

- 1. Applicant's amendment filed 5/14/2004 is acknowledged and entered. Claims 13-53 have been canceled.
- 2. Claims 1-12 are pending.
- 3. This application claims priority to three provisional applications. They are 60/181,321 filed 2/9/2000; 60/205,269 filed 5/18/2000; and 60/209,158 filed 6/2/2000.

Election/Restrictions

- 4. Applicant has elected the following species for the elected invention (Claims 1-12) in the reply filed on 4/9/2003:
 - a) A species of first gene product: vascular endothelial growth factor (VEGF).
 - b) A species of second gene product: proteins.
- 5. Claims 7-8, and 10-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to *nonelected species*, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/9/2003.

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Withdrawn Rejections

6. The rejection of claims 1-2, and 4 under 35 USC 102(b) as being anticipated by Wilson et al. (US Patent 6,001,557) has been withdrawn in light of applicant's arguments. However, upon further consideration, a new ground(s) of rejection is made in view of van Zonneveld et al. (US Patent 6,447,768 B1) and Schatz et al. (US Patent 6,156,511).

- 7. The rejection of claims 1-2, and 4 under 35 USC 102(e) as being anticipated by M^cVey et al. (US Patent 6,440,728 B1) has been withdrawn in light of applicant's arguments. However, upon further consideration, a new ground(s) of rejection is made in view of van Zonneveld et al. (US Patent 6,447,768 B1) and Schatz et al. (US Patent 6,156,511).
- 8. The rejection of claims 1-6, 9, and 12 under 35 USC 103(a) as being obvious over Wilson et al. (US Patent 6,001,557) has been withdrawn in view of applicant's arguments. However, upon further consideration, a new grounds of rejection is made in view of van Zonneveld et al. (US Patent 6,447,768 B1) and Schatz et al. (US Patent 6,156,511).

New Rejections

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Schatz et al. (US Patent 5,733,731).

The instant claim 1 briefly recites a library of viral vectors. This instant claim is interpreted as a library of vectors wherein each member comprises a common first heterologous DNA encoding a first gene product and a second heterologous DNA encoding a second gene product that varies between the members of the library.

Schatz et al. disclose a random peptide library (see e.g. Abstract; col. 2, lines 37-43).

Claim 27 of Schatz et al. recites a random peptide library wherein each member of the recombinant DNA vector comprises a DNA binding protein (refers to the first gene product of the instant claim 1) and a random peptide (refers to the second gene product of the instant claim 1) wherein members differ from other members with respect to the sequence of the random peptide (refers to the limitation wherein the second gene product varies between the members of the library of the instant claim 1). The vector also includes a promoter (see e.g. col. 9, lines 9-17) (refers to instant claim 3). Therefore the library of Schatz et al. anticipates the presently claimed vector library.

11. Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Schatz et al. (US Patent 6,156,511; *filing date 1/21/1998*).

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The instant claim 1 briefly recites a library of viral vectors. It is interpreted as a library of vectors wherein each member comprises a common first heterologous DNA encoding a first gene product and a second heterologous DNA encoding a second gene product that varies between the members of the library.

Schatz et al. disclose a library of vectors (see e.g. Abstract; col. 2, lines 39-55; and Claim 32). Each member of the vector library comprises a DNA sequence encoding a DNA binding protein (refers to the first gene product of the instant claim 1), a promoter (refers to instant claim 3), and a coding sequence for a random peptide (refers to the second gene product of the instant claim 1) wherein each member differs from the other with respect to the sequence of the peptide (refers to the limitation wherein the second gene product varies between the members of the library of the instant claim 1). Therefore the library of Schatz et al. anticipates the presently claimed vector library.

12. Claims 1-6, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by van Zonneveld et al. (US Patent 6,447,768 B1; *filing date 12/29/1999*).

The instant claim 1 briefly recites a library of viral vectors. It is interpreted as a library of vectors wherein each members comprises a common first heterologous DNA encoding a first gene product and a second heterologous DNA encoding a second gene product that varies between the members of the library.

van Zonneveld et al. disclose nucleic acid delivery carrier that includes virus vectors such adenoviral vectors and adeno-associated viral vectors (Abstract; col. 3, lines 18-30, and 51-56).

The viral vectors comprise recombinant adenoviral vectors (refers to instant claim 2) containing

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a common nitric oxide synthase (refers to the first gene product of the instant claim 1), a CMV promoter (refers to instant claim 3), and a sequence encoding either bFGF or VEGF (refers to the second gene product and the limitation wherein the second gene product varies between the members of the library of the instant claim 1) (col. 5, lines 5-24; col. 6, line 23-28). Thus the viral vectors of van Zonneveld et al. anticipate the presently claimed library of viral vectors.

Response to Arguments

- 13. Applicant's arguments with respect to claims 1-6, 9, and 12 have been considered but are moot in view of the new ground(s) of rejection.
- 14. Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

15. The following is a statement of reasons for the indication of allowable subject matter:

The limitation that the first gene product is a vascular endothelial growth factor (VEGF) of the claimed library of viral vectors wherein each members of the library comprises a common first heterologous DNA encoding a first gene product and a second heterologous DNA encoding a second gene product that varies between the members of the library is not taught or suggested by the cited prior art.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct

August 8, 2004

PADMÁSHRI PONNALURI PRIMARY EXAMINER